



PATENT SPECIFICATION

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COMPLETE SPECIFICATION

Catheters and like Drainage Tubes and the Manufacture thereof

We, ERNEST ALBERT MANSELL, a British Subject, and J. G. FRANKLIN & SONS LIMITED, a British Company, both of 15, Colvestone Crescent, Dalston, London, E.8, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to catheters and like drainage tubes (hereinafter generically referred to as "catheters") and the manufacture thereof.

It has been proposed to form a catheter with a solid distal end portion ahead of the drainage eyelet or eyelets. With such a catheter, compared with a hollow ended catheter, there is less high flexibility of the distal end, a feature which can be of importance in certain instances of use. The process of manufacture of such solid distal ended catheters has been somewhat complicated however and it is an object of the invention to enable this process to be simplified.

According to the invention a catheter body with a solid distal end is produced from a liquid composition, e.g., latex, by causing the composition to set in a space, having the desired form of the catheter, defined between a former and an outer wall which extends beyond the tip of the former to an extent according to the required length of the solid end so that the said end is formed *in situ*.

A catheter may be produced according to the invention from any suitable substance employed in the production of this type of article by dipping, e.g., liquid rubber or plastic compositions such as natural or artificial aqueous dispersions of rubber, (prevulcanised or including vulcanising ingredients if desired), or an organosol, e.g., a dispersion of polyvinyl-chloride powder in a liquid plasticiser. If latex is employed, we may use normal latex, but the more viscous concentrated types are preferred, and we prefer to employ centrifuged latex as it gives a

quick drying rubber coating with high tensile properties.

In one way of carrying out the invention we employ a former which is introduced into a tube, such as a glass tube, the former and tube being dimensioned so that the space between them has the shape of the solid ended catheter required. The tube may first be filled with a liquid composition e.g., prevulcanised latex, the former then being introduced into the composition in the tube, or the composition may be supplied to the tube after the former has been positioned. Setting of the composition is then allowed to proceed until the catheter body is strong enough to enable it to be withdrawn on the former from the tube.

The setting of the composition may be determined in any suitable manner. Where latex is used, setting or gelling may be effected with the aid of coagulating means or by the action of heat or both, e.g., according to U.K. Patent 284,608 or 330,520 and where a coagulant is employed this may be coated onto the former before the latter is introduced into the tube. An example of a coagulant which serves well is a 50% solution of calcium nitrate in water or alcohol. Where an organosol is used gelling will be effected by heating to convert the organosol into a solution of plasticiser in plastic.

The length and shape of the solid distal end of the catheter, as determined by the shape and relative spacing of the tip of the former and the end of the form space, may be widely varied. For example, it may be cylindrical with a semi-spherical free end, or it may be bulbous or olivary.

The eyeletting of the catheter body may be effected in any desired manner. An eyelet may be positioned so that it is bounded on its side nearer the distal end by the solid distal end portion of the catheter, thereby eliminating any cul de sac formation such as obtains with hollow ended catheters and is liable to lead to undesirable loss of asepsis.

In order that the invention may be the

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more readily understood, it will be hereinafter be further described by way of example with reference to the drawings accompanying the provisional specification in which:—

Fig. 1 illustrates a former as used in the catheter manufacture,

Fig. 2 shows the former in position in a co-operating tube, and

Figs. 3 and 4 are a fragmentary sectional elevation and a fragmental plan respectively of the distal end of an eyeletted catheter body as formed using the apparatus shown in Figs. 1 and 2, and having the eyelets formed therein.

Referring now to the drawings, a former A having an exterior form corresponding with the desired interior form of the catheter body is used in conjunction with a glass tube B to define a form space for the catheter. Pre-vulcanised latex is poured into the tube B and the former A, coated with a suitable coagulating agent, is then introduced into the tube. The inserted position of the tube is shown in Fig. 2, the tip of the former being spaced from the end of the tube by a distance corresponding with the desired length of the solid end of the catheter. The former is left in position in the glass tube to allow the latex to gel under the action of the coagulant, and, if necessary, heat.

When setting or gelation is sufficiently complete the former is withdrawn from the tube with the dried or coagulated latex thereon. If desired further latex dips are now added. After formation of the catheter body, it is removed from the former and washed and dried, and an eyelet D is then formed in its tubular wall. The former A has a tapered tip, giving a tapered end to the tubular passage in the catheter. The eyelet D is formed partly in the solid end portion of the catheter, the inner end face of the said solid portion being shaped so that it slopes beneath the eyelet from that part of its edge which lies nearer the distal end of the catheter. The wider ends of the former and the tube are flared to give a flared form to the wall of the catheter at its corresponding end.

In addition to or instead of coating the coagulating agent onto the former it may be coated onto the interior of the tube B.

What we claim is:—

1. A method of producing a catheter body having a solid distal end from a

liquid composition, e.g., latex, wherein the composition is caused to set in a space, having the desired form of the catheter, defined between a former and an outer wall which extends beyond the tip of the former to an extent according to the required length of the solid end so that the said end is formed *in situ*.

2. A method according to Claim 1, wherein after setting of the composition to form the body of the catheter an eyelet is formed in the said body next to the solid end so as to avoid any cul de sac formation at the distal end of the catheter.

3. A method according to Claim 2 wherein an inner face of the solid end is shaped so as to slope beneath the eyelet from that part of its edge which is nearer the distal end of the catheter.

4. A method according to any preceding claim, wherein after setting of the composition to form the body of the catheter, the body is removed on the former from within the outer wall, and one or more further coatings are then applied to the coated former.

5. A method according to any preceding claim, wherein the liquid composition is a natural or artificial aqueous dispersion of rubber.

6. A method according to any preceding claim wherein the liquid composition is supplied to a tube into which a former has been or is then introduced, the former and tube defining the space corresponding to the desired form of the catheter.

7. A method according to any preceding claim, wherein the composition employed is adapted to be coagulated with the aid of a coagulating agent and wherein the former or the inside face of the outer wall or both are coated with a coagulating agent.

8. A catheter body when produced by the method according to any preceding claim.

9. A method of producing a catheter with a solid distal end substantially as herein described with reference to the drawings accompanying the provisional specification.

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PROVISIONAL SPECIFICATION

Catheters and like Drainage Tubes and the Manufacture thereof

We, ERNEST ALBERT MANSELL, a British Subject, and J. G. FRANKLIN & SONS LIMITED, a British Company, both of 15, Colvestone Crescent, Dalston, London, E.8, do hereby declare this inven-

tion to be described in the following statement:—

The present invention concerns solid distal or forward ended flexible tubes or catheters, particularly urethral catheters,

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and the manufacture thereof from liquid rubber or plastic compositions, e.g., natural or artificial aqueous dispersions of rubber, or an organosol, e.g., a dispersion of polyvinylchloride powder in a liquid plasticiser.

The rubber composition may contain vulcanising ingredients or may consist of pre-vulcanised dispersions.

It has been proposed to form flexible tubes by a dipping process from latex and those ends intended to be distal ends of the catheters have had eyelets formed therein in the desired positions.

This however is open to the objection that the hollow and eyeletted distal ends form cul de sacs which can lead to undesirable loss of asepticism and can have too high a degree of flexibility.

Now, the primary object to the present invention is to build up a solid tip to the distal end of the tube so that the tube wall and solid tip are formed in one piece, e.g., of rubber, from latex.

In one way of carrying out our invention we produce the catheter on a former which is introduced into a tube containing or subsequently supplied with rubber dispersion which may be pre-vulcanised, the space between former and tube having the shape of the solid ended catheter required, and setting or gelling of the dispersion is allowed to proceed until the gel is strong enough to enable the coated former and the solid tip to be removed from the tube. Further dip coatings may be added. Each coat may be dried or coagulated before the subsequent dip.

Setting or gelling of latex may be effected with the aid of coagulating means or by the action of heat, or both, e.g., according to U.K. Patent 284,608 or 330,520.

The coagulant may be coated on the former or on the wall of the tube or on both.

The end of the former corresponding to the distal end of the catheter may be tapered outwards and the eyelet may be formed so that the inwardly and rearwardly sloping wall is exposed to the exterior of the catheter, while the open end of the tube may be flared and the corresponding portion of the former may be given a following contour.

In length and shape the solid distal end may be widely varied. For example, it may be cylindrical with a semi-spherical free end, or it may be bulbous or olivary.

For the purposes of the present invention we may use normal latex, but the more viscous concentrated types are preferred and we prefer to employ centri-

fuged latex as it gives a quick drying rubber coating with high tensile properties.

An example of coagulant which serves well for the purposes of the present invention is a 50% solution of calcium nitrate in water or alcohol.

By the following experimental method catheters have been produced having a solid distal end which is entirely composed of latex and is formed *in situ*.

A glass tube internally having the external shape of the required catheter is filled with latex (the latex used was pre-vulcanised); a former on which the catheter is to be produced is coated with a coagulating agent and immersed concentrically in the tube containing latex. The distal end of the former does not reach the end of the glass tube, the rounded bottom of which extends beyond the tip of the former to an extent depending upon the length of solid tip required.

The former is left in position in the glass tube containing the latex to allow the latex to gel under the action of the coagulant and, if necessary the heat.

When setting or gelation is sufficiently complete and the gel is strong enough the former is removed with the dried or coagulated latex thereon. Further latex dips may now be added. When dry the catheter is removed from the former and is washed and dried and an eye or eyes are cut therein in the required position or positions.

In a modification of the above method the coagulant coated former may be positioned in the tube before the latex is supplied thereto.

The latex may be gelled solely by the action of heat.

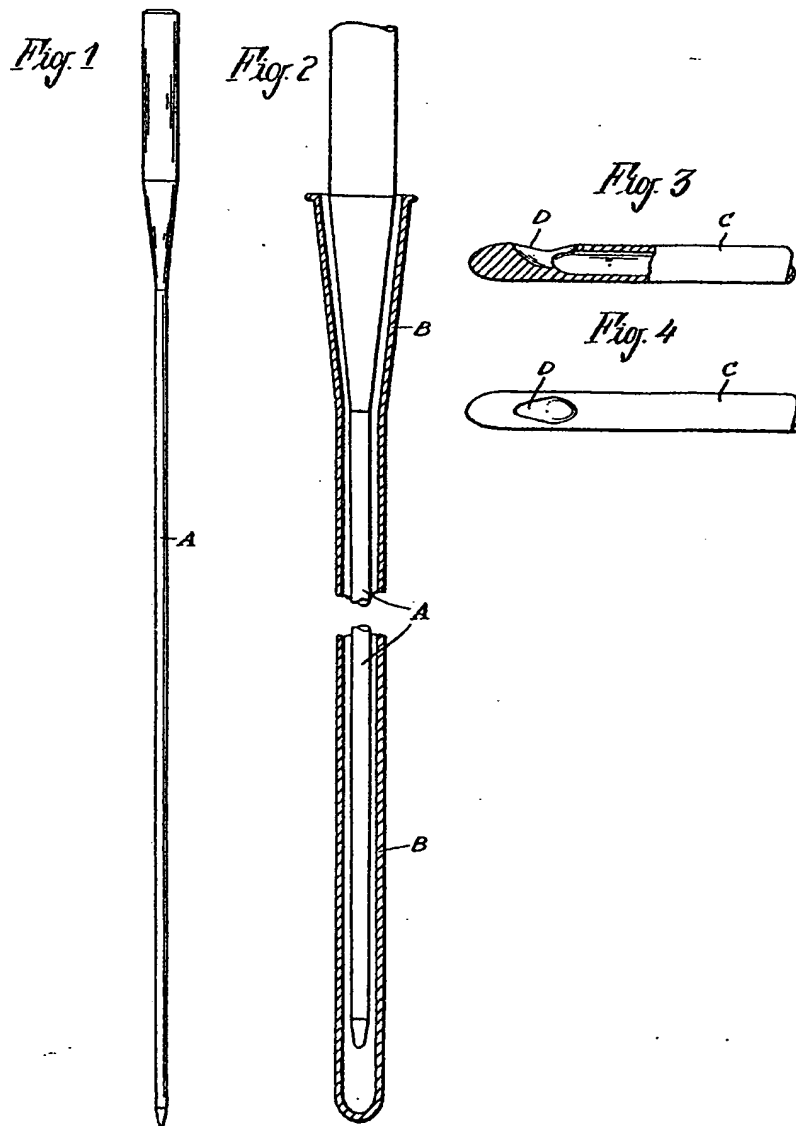
The tube may first be lined with a coagulant, the former—coagulant coated or not—placed in position in the tube and latex then supplied thereto.

Using a plastic composition such as aforesaid the invention may be carried out *mutatis mutandis* similarly to that above described.

The invention is illustrated by way of example in the accompanying drawings in which A is the former, B the tube, C the catheter body and D the eyelet. Fig. 1 illustrates the former A, Fig 2 the former A within the dipping tube B and Figs. 3 and 4 are a part fragmentary part sectional side elevation and plan respectively of the distal end of the catheter body C shewing the eyelet D.

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